



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 09/366,081 | 08/02/1999 | SYDNEY BRENNER | 802-04RE | 2643 |

22918 7590 03/22/2005

PERKINS COIE LLP
P.O. BOX 2168
MENLO PARK, CA 94026

| |
|----------|
| EXAMINER |
|----------|

ZARA, JANE J

| | |
|----------|--------------|
| ART UNIT | PAPER NUMBER |
|----------|--------------|

1635

DATE MAILED: 03/22/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/366,081

Applicant(s)

BRENNER, SYDNEY

Examiner

Jane Zara

Art Unit

1635

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 October 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-6, 9, 10, 12 and 13 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1-3, 10, 12 and 13 is/are allowed.
- 6) ☒ Claim(s) 5, 6 and 9 is/are rejected.
- 7) ☒ Claim(s) 4 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

This Office action is in response to the communication filed 10-7-04.

Claims 1-6, 9, 10, 12 and 13 are pending in the instant application.

Drawings

The drawings were received on 10-7-04. These drawings are accepted.

Reissue Applications

Applicant is reminded of the continuing obligation under 37 CFR 1.178(b), to timely apprise the Office of any prior or concurrent proceeding in which Patent No. 5,654,413 is or was involved. These proceedings would include interferences, reissues, reexaminations and litigation.

Applicant is further reminded of the continuing obligation under 36 CFR 1.56, to timely apprise the Office of any information which is material to patentability of the claims under consideration in this reissue application.

These obligations rest with each individual associated with the filing and prosecution of this application for reissue. See also MPEP §§ 1404, 1442.01 and 1442.04.

Response to Arguments and Amendments

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Withdrawn Objections and Rejections

Any rejections not repeated in this Office action are hereby withdrawn.

Maintained Objections and Rejections

Response to Arguments and Amendments

The reissue oath/declaration filed with this application is defective because it fails to identify at least one error which is relied upon to support the reissue application. See 37 CFR 1.175(a)(1) and MPEP § 1414. The oath does not specifically state a correlation between specified claims and the error.

Claims 1-6, 9, 10, 12 and 13 are rejected as being based upon a defective reissue oath under 35 U.S.C. 251 as set forth above. See 37 CFR 1.175.

The nature of the defect(s) in the oath is set forth in the discussion above in this Office action.

The amendment filed 10-7-04 proposes amendments that do not comply with 37 CFR 1.173(b), which sets forth the manner of making amendments in reissue applications. A supplemental paper correctly amending the reissue application is required.

Throughout the prosecution of the instant Reissue Application, Applicants have submitted amendments to the claims that are not in the proper format for Reissue Applications, which should reflect all amendments relative to the issued claims, not the changes relative to the prior pending claims (e.g. ***new claims 5, 6, 9, 10, 12 and 13***

should be underlined). See MPEP 1453 for proper format for filing amendments in a Reissue Application. Applicants must submit amended and new claims in the proper format in order for the response to this Office action to be considered fully responsive. Additionally, it is required that Applicants provide a courtesy copy of the claims in a format, wherein the claims are marked up relative to the prior pending versions of the claims - to better facilitate the examination process.

Claims 5 and 6 rejected under 35 U.S.C. 103(a) as being unpatentable over Wang and Hornes for the same reasons of record set forth in the Office actions mailed 4-9-01 and 4-8-04.

Applicant's arguments filed 10-7-04 have been fully considered but they are not persuasive. Applicants argue that Wang (EP 0304845) does not teach how one would supply thousands of distinct labels to label thousands of different probes and therefore one would not be able to envision the use of thousands of different probes from the teachings of Wang. Applicants argue further that the invention taught by Hornes (USPN 5,512,439) could comprise any number of particles having 10^3 to 10^6 copies of the same molecule, while the instantly claimed composition includes at least ten thousand microparticles, each containing a different polynucleotide and therefore would not be obvious from the combined teachings of Wang and Hornes.

Contrary to Applicants' assertions, Wang teaches a plurality of probes attached to microparticles, wherein the plurality of probes comprises sequences that differ from each other: The compositions taught by Wang comprise a plurality of polynucleotides

Art Unit: 1635

which are fragments of target polynucleotides or complements of fragments, wherein all different polynucleotides in this plurality are attached to different microparticles (see e.g. col. 3-4 of Wang). Hornes teaches advantages of attaching thousands of (e.g. 10^3 – 10^5) cDNA polynucleotides to microbeads (see col. 5 of Hornes). The combined teachings therefore properly render the claimed invention obvious to one of ordinary skill in the art. Since this is an obviousness rejection, neither Wang nor Hornes need to anticipate the claimed invention in its entirety. It would have been obvious to one of ordinary skill in the art to utilize the teachings of Wang and Hornes to provide a composition comprising a plurality of polynucleotides, wherein 10^4 to 10^5 polynucleotides are each attached to different microparticles. Therefore the instant obviousness rejection is maintained.

New Rejections and Objections

Claim 9 is rejected under 35 U.S.C. 251 as being an improper recapture of broadened claimed subject matter surrendered in the application for the patent upon which the present reissue is based for the same reasons of record set forth the Office

Claim 9 is rejected under 35 U.S.C. 251 as being an improper recapture of broadened claimed subject matter surrendered in the application for the patent upon which the present reissue is based. See *Pannu v. Storz Instruments Inc.*, 258 F.3d 1366, 59 USPQ2d 1597 (Fed. Cir. 2001); *Hester Industries, Inc. v. Stein, Inc.*, 142 F.3d 1472, 46 USPQ2d 1641 (Fed. Cir. 1998); *In re Clement*, 131 F.3d 1464, 45 USPQ2d 1161 (Fed. Cir. 1997); *Ball Corp. v. United States*, 729 F.2d 1429, 1436, 221 USPQ

Art Unit: 1635

289, 295 (Fed. Cir. 1984). A broadening aspect is present in the reissue which was not present in the application for patent. The record of the application for the patent shows that the broadening aspect (in the reissue) relates to subject matter that applicant previously surrendered during the prosecution of the application. Accordingly, the narrow scope of the claims in the patent was not an error within the meaning of 35 U.S.C. 251, and the broader scope surrendered in the application for the patent cannot be recaptured by the filing of the present reissue application.

In Paper No. 7, mailed 3-19-96, the Examiner stated that the nearest prior art does not provide motivation or suggest increasing the minimum number of mismatches between a given tag and incorrect tag complements to at least two mismatches. Claim 9 does not require this limitation (*i.e.* See line 6 of claim 9, indicating that “perfectly matched duplexes” be formed between tag complements and oligonucleotide tags). Claim 9, therefore, by omitting the limitation of at least two mismatches between a tag and its complement, broadens the scope of the claimed subject matter to include subject matter surrendered during the prosecution of the issued patent and does not contain the specific element the Examiner said was necessary to be free of the prior art.

Claim Objections

Claim 4 is objected to because of the following informalities: In line 1 of claim 4, “wherein said microparticles is selected” appears to be grammatically incorrect (e.g. changing “microparticles” to – microparticle -- would be remedial). Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-6, 9, 10, 12, and 13 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The metes and bounds of *spacially discrete regions* (e.g. see claim 1, line 2), *a uniform population of substantially identical oligonucleotide tag complements* (e.g. see claim 1, line 3), *fragments of a target polynucleotide* (e.g. see claim 5, line 3) cannot be determined. Appropriate clarification is required.

It is unclear in claim 5, lines 5-8, how “each microparticle has polynucleotides of the plurality attached thereto,” yet “all different polynucleotides in the plurality are attached to different microparticles.” These two conditions seem to contradict each other (e.g. how can each microparticle have polynucleotides of the plurality and, at the same time, fulfill the requirement of having only one type of polynucleotide per microparticle?). Appropriate clarification is requested.

In claim 6, line 2, “said microparticles” is unclear: This claim depends from claim 5, which mentions mixtures of microparticles (line 4), single microparticles (line 5) and different microparticles (line 7). Appropriate clarification is requested.

In claim 6, lines 1-2, “said polynucleotides” is unclear: This claim depends from claim 5, which mentions different polynucleotides (line 2), target polynucleotide (line 3),

Art Unit: 1635

polynucleotides of the plurality (line 5), and all different polynucleotides in the plurality (line 6). Appropriate clarification is requested.

In claim 9, line 4, the phrase "tag complements are attached to each of said microparticles of said mixture" is vague and unclear: Does this mean that tag complements are attached to each microparticle in the mixture? If so, then "microparticles" should be singular (microparticle), not plural. Appropriate clarification is requested.

Claim 9 recites the limitation "said fragments of said plurality" in line 5. There is insufficient antecedent basis for this limitation in the claim.

Claim 9 recites the limitation "said cDNAs or DNA fragments" in line 7. There is insufficient antecedent basis for this limitation in the claim.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-6, 9, 10, 12, and 13 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are drawn to compositions comprising *a uniform population of substantially identical oligonucleotide tag complements*. In addition, the claims are drawn to *fragments of a target polynucleotide* and solid phase support having one or

Art Unit: 1635

more *spacially discrete regions*. The specification and claims do not describe the elements that are essential to defining these genera. The specification and claims do not indicate or adequately describe the attributes concisely shared or encompassed by the members of the genera comprising *a uniform population of substantially identical oligonucleotide tag complements*, comprising *fragments of a target polynucleotide* or comprising solid phase support having *one or more spacially discrete regions*. The scope of the claims includes numerous structural variants and the genera are highly variant because a significant number of structural differences between members of each genus is permitted. Concise structural features that could distinguish structures within the genera from others are missing from the disclosure. The general knowledge and level of skill in the art do not supplement the omitted description because specific, not general guidance is what is needed (e.g. What is encompassed by substantially identical oligonucleotide tag complements? What is the size or structure of the fragments? What determines one or more spatially discrete regions?). The specification fails to teach or adequately describe a representative number of species in the genus such that the common attributes or characteristics concisely identifying members of the proposed genera comprising either *a uniform population of substantially identical oligonucleotide tag complements*, *fragments of a target polynucleotide* or a solid phase support having *one or more spacially discrete regions* are exemplified. One of skill in the art would reasonably conclude that the disclosure fails to provide a representative number of species to describe the genera claimed. Thus, Applicant was not in possession of the claimed genera comprising a uniform population of substantially

identical oligonucleotide tag complements, fragments of a target polynucleotide or a solid phase support having one or more spacially discrete regions.

Conclusion

Certain papers related to this application may be submitted to Art Unit 1635 by facsimile transmission. The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 C.F.R. § 1.6(d)). The official fax telephone number for the Group is **703-872-9306**. NOTE: If Applicant *does* submit a paper by fax, the original signed copy should be retained by applicant or applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers in the Office.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Jane Zara** whose telephone number is **(571) 272-0765**. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John LeGuyader, can be reached on (571) 272-0760. Any inquiry regarding this application should be directed to the patent analyst, Katrina Turner, whose telephone number is (571) 272-0564. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for

Art Unit: 1635

published applications may be obtained from either Private PAIR or Public PAIR.

Status information for unpublished applications is available through Private PAIR only.

For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

93 TC 1600